Long-term clinical outcomes of Chinese diabetic patients after coronary revascularization with drug-eluting stents: a retrospective comparative cohort study

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Background: Compared to bare-metal stent implantation, coronary drug-eluting stent (DES) implantation is more likely to reduce restenosis and the need for a subsequent repeat revascularization procedure. Diabetes increases the risk of coronary heart disease and the population of diabetic patients has increased significantly in China in recent years. It's essential to know more about the outcome in these patients underwent DES implantation. To date, the long-term safety and efficacy of coronary DES implantation in Chinese patients with diabetes has rarely been investigated.

Methods: In this study, according to inclusion and exclusion criteria, 580 patients who underwent DES implantations between July 2014 and January 2016 were included and divided into the diabetic group (n=173) and non-diabetic group (n=407). Clinical baseline characteristics and follow-up outcomes were collected from electronic medical record. Serial clinical follow-up was conducted at 1-, 3-, and 5-year. The primary end point was a composite of major adverse cardiac events (MACEs), including cardiac death, recurrent myocardial infarction (re-MI), and target lesion revascularization (TLR) in 5-year follow-up. The long-term outcomes observed in the 5-year follow-up period were compared between the diabetic and non-diabetic patients.

Results: Non-cardiac death was more common in the diabetic than non-diabetic patients in the 5-year follow-up period (8.7% *vs.* 3.2% P=0.00). Conversely, the risk of occurrence of MACEs, cardiac death, re-MI, and TLR were comparable. The all-cause mortality rate in 5-year follow-up was higher in the diabetic than non-diabetic patients (14.5% *vs.* 6.1%, P=0.00). The incidence of stent thrombosis was also comparable between the diabetic and non-diabetic patients.

Conclusions: Compared to the non-diabetic patients, the diabetic patients were at higher risk for all-cause mortality after coronary DES implantation during the long-term follow-up period.

Keywords: Drug-eluting stents (DES); coronary heart disease; diabetes; safety

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Introduction

In China, cardiovascular diseases are a leading cause of death and affect over 40% of Chinese residents in the mainland (1,2). Coronary artery disease (CAD) represents a major threat to people's health worldwide (3). Diabetes has been proven to be a major risk factor for the development of CAD (4,5), and it also increases the difficulty of percutaneous coronary interventions (PCIs) for patients with CAD and the risk of death (6-8). It's estimated that in China, there are about half CAD patients suffered from diabetes, and CAD patients with diabetes have high mortality and high risk of stent failure (1).

After decades of progress in materials and technology, drug-eluting stent (DES) implantation has been shown to have significant clinical and angiographic benefits for patients with diabetes in many clinical studies and practice compared to plain balloon angioplasty and bare metal stent (BMS) implantation (6,7). Additionally, some patients do not benefit from DES implantation due to stent failure related to in-stent restenosis (ISR), stent thrombosis (ST), and other problems (9,10), especially in patients with diabetes (4).

Stent failure can result in the recurrence of myocardial ischemia, heart failure, and even sudden death (11). However, the efficacy and safety of DES implantation in Chinese CAD patients with diabetes over the long term have not been well investigated. To better understand the long-term efficacy and safety of DES for CAD patients with diabetes, we observed and compared the clinical outcomes of DES implantation between diabetic and non-diabetic patients over a 5-year follow-up period. We present the following article in accordance with the STROBE reporting checklist (available at https://atm.amegroups.com/article/view/10.21037/atm-22-4517/rc).

Methods

Study population

This is a retrospective comparative cohort study. Patients who underwent percutaneous interventions with sirolimus-eluting stents or paclitaxel-eluting stents between July 2014 and January 2016 in Chinese PLA General Hospital were retrospectively enrolled in the present study according to the inclusion and exclusion criteria. To be eligible for inclusion in this study, patients had to meet the following inclusion criteria: (I) be aged ≥18 years; (II) had undergone DES implantation due to CAD for the 1st time; (III) had been treated with standard medication after DES implantation; and (IV) had been regularly followed-up for at least 5 years. Patients were excluded from the study if they met any of the following exclusion criteria: (I) had cancer; (II) had a rheumatic disease; and/or (III) had missing clinical or follow-up information. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Ethics Committee of Chinese PLA General Hospital (No. S2020-012-03). Informed consent was taken from all the patients.

Data collection and clinical follow-up

Relevant data (including demographic information, disease history, laboratory test results, examination findings, PCI information, medication therapies, and outcome data) were collected. The follow-up was conducted at the outpatient clinic regularly at 1-, 3-, and 5-year and any time as required after the 1st revascularization with a DES. After the DES implantation, all the patients were treated with dual antiplatelet therapy, including aspirin (100 mg daily) and clopidogrel (75 mg daily) for at least 1 year. These patients also received moderate to high intensity statin therapy (mainly atorvastatin at 20–40 mg daily). The diabetic patients were all treated with anti-diabetic drugs according to the guideline (12).

Study end points and definitions

The primary end point of the present study was a composite of major adverse cardiac events (MACEs), including cardiac death, recurrent myocardial infarction (re-MI), and stented target lesion revascularization (TLR). The secondary end points included the individual components of the MACEs, all-cause mortality, and ST. In this study, the diagnosis of diabetes mellitus was established according to the criteria in the "Guidelines for Patients with Type 2 diabetes in China" (12). ISR was defined as stenosis of at least 50% of the minimal luminal diameter in the target lesion at the follow-up coronary angiography (13). TLR was defined as any symptom driven coronary artery bypass graft or repeat PCI (balloon angioplasty or repeat stent implantation) for ISR, or the occlusion of the target lesion (14). ST was classified using the Academic Research Consortium (ARC) definition (15).

Statistical analysis

SPSS software (version 22.0, IBM, Chicago, USA) was

Table 1 Comparison of the clinical and angiographic characteristics at the baseline between the 2 groups

Characteristics	Diabetic patients (n=173)	Non-diabetic patients (n=407)	P value
Age (year, mean ± SD)	60.08±11.58	64.01±10.79	0.00
Male (n, %)	127 (73.41)	342 (84.03)	0.00
Smoking (n, %)	66 (38.32)	181 (44.5)	0.16
Diagnosis (n, %)			
Stable angina	3 (1.7)	14 (3.4)	0.27
Unstable angina	120 (69.4)	261 (64.1)	0.22
NSTEMI	7 (4.0)	19 (4.7)	0.74
STEMI	43 (24.9)	113 (27.8)	0.47
Risk factors (n, %)			
Previous MI	13 (7.5)	47 (11.5)	0.14
Hypertension	131 (75.7)	246 (60.4)	0.00
Hyperlipidemia	27 (15.6)	81 (19.9)	0.22
Coronary angiography (n, %)			
No. of lesions (mean ± SD)	2.21±0.43	2.01±0.36	0.00
No. of stents (mean ± SD)	2.15±0.43	1.87±0.32	0.00
Single vessel disease (n, %)	41 (23.7)	131 (32.2)	0.04
Double vessel disease (n, %)	51 (29.5)	124 (30.5)	0.81
Triple vessel disease (n, %)	81 (46.8)	152 (37.3)	0.03
Stents site (n, %)			
LM	10 (2.7)	9 (1.2)	006
LAD	155 (41.7)	368 (47.9)	0.05
LCX	77 (20.7)	131 (17.0)	0.13
RCA	130 (34.9)	261 (33.9)	0.74

NSTEMI, non-ST elevation myocardial infarction; STEMI, ST elevation myocardial infarction; ST, stent thrombosis; MI, myocardial infarction; LM, left main; LAD, left anterior descending; LCX, left circumflex artery; RCA, right coronary artery.

used for the statistical analysis. The continuous data are expressed as the mean ± standard deviation (SD), and comparisons between the 2 groups were conducted using the Student *t*-test. The categorical data are expressed as the number (percentage), and comparison between the 2 groups were conducted using the Chi-square test or Fisher's exact test. A two-sided P value <0.05 was considered statistically significant.

Results

A total of 580 patients were included in the final analysis. The patients had an average age of 62.84 years (range, 38–77 years). Among the patients, 469 were male (80.86%). The patients were divided into the diabetic group, comprising 173 patients (29.83), and the non-diabetic group, comprising 407 patients (70.17%). The baseline characteristics of the patients are set out in *Table 1*. Compared to the non-diabetic group, the diabetic group had more hypertension (75.7% *vs.* 60.4%, P=0.00), multivesicular diseases (46.8% *vs.* 37.3%, P=0.03), females (27.6% *vs.* 16.0%, P=0.00), and a lower average age (60.08±11.58 *vs.* 64.01±10.79, P=0.00).

We found that compared to the non-diabetic patients, the diabetic patients were at increased risk for mortality (14.5% *vs.* 6.1%, P=0.00), including all-cause mortality (8.7% *vs.* 3.2%, P=0.00) and cardiac death (5.8% *vs.* 2.9%,

P=0.10) during the 0–5-year follow-up period. The diabetic patients also had a higher incidence of re-MI (1.7% *vs.* 0, P=0.02), all-cause mortality (4.6% *vs.* 1.2%, P=0.02), and MACEs (9.2% *vs.* 4.4%, P=0.03) during the 3–5-year follow-up period than the non-diabetic patients. However, there were no significant differences between the diabetic and non-diabetic patients in terms of the primary events, including the MACEs, cardiac death, re-MI and target vessel revascularization (TVR) during the 0–3-year and 0–5-year follow-up periods (all P>0.05) (see *Table 2*). The risks of MACEs in the 3 groups were 4.6% *vs.* 4.4% at 1 year (P=0.91), 10.4% *vs.* 9.6% at 3 years (P=0.76) and 19.7% *vs.* 14.3% at 5 years (P=0.10). An increasing trend was observed in the MACE rate in both the diabetic and nondiabetic patients who received DES implantations, but the rate of the diabetic patients increased faster than that of the non-diabetic patients, especially in the long-term.

The occurrence rates of early (1.7% *vs.* 0.7%, P=0.52), late (0.6% *vs.* 0.5%, P=0.79), and very late (1.7% *vs.* 1.2%, P=0.93) thrombosis and overall thrombosis (4.0% *vs.* 2.5%, P=0.30) did not differ between the diabetic and non-diabetic patients (see *Table 3*).

Discussion

In the era of coronary stenting, even with standard medication therapy, including intensive statin, dual antiplatelet, and intensive glycemia-lowering, diabetes remains a risk factor for the poor prognosis of patients with CAD (16-18). Diabetes has long been considered a poor prognostic factor for angiographic and clinical outcomes after PCI (18,19). Previous studies have shown that diabetes increases the risk of the onset of MI or cardiac death in patients with established CAD (20,21).

The main finding of the present study was that there was a 2.4-fold increase in the mortality of diabetic patients compared to non-diabetic patients over the 0–5-year follow-up period. Despite the increase in the risk of death, the diabetic patients still benefited from the DES implantations. Similar to previous findings (22), we found that the CAD patients with diabetes had a higher risk of mortality after DES implantation than the CAD patients without diabetes.

In the SIRTAX LATE trial, the 5-year follow-up outcomes revealed that all-cause mortality (18.9% *vs.* 8.0%; P<0.0001) and cardiac mortality (11.4% *vs.* 4.3%; P<0.0001) were higher in patients with diabetes than patients without diabetes (23,24). However, there were no difference in the incidences of MI (6.5% *vs.* 6.8%; P=0.99), symptom-driven TLR (14.4% *vs.* 14.1%; P=0.67), and TLR (16.9% *vs.* 17.3%; P=0.81) between the patients with and without diabetes (23). The results of the present study support the findings of this previous study. Taken together, the findings of the previous study and the present study indicate that clinicians should be aware that following DES implantation, patients with diabetes have a poorer prognosis than patients without diabetes, and explain each patient's situation to the patient and/or his/her family members as appropriate.

The mortality remained increased in diabetic patients after DES implantation, but there were no differences in terms of the risk of MACE, MI, and TLR between diabetic and non-diabetic patients. However, the diabetic patients had higher incidences of MACEs and re-MI than the non-diabetic patients in the follow-up period, especially in the long-term. This finding is notable because diabetes has long been proven to be a risk factor for in-lesion restenosis after balloon angioplasty and BMS implantation. These findings support those reported in earlier studies (25,26).

Some previous observational studies have noted that diabetes is an independent risk factor for early and late ST after coronary DES implantation (27,28). The underlying mechanism for ST in diabetic patients after DES implantation mainly involves poor endothelialization, endothelial dysfunction, stent polymer reactions, strut fractures, positive remodeling with stent malposition, or new plaque rupture either adjacent to or within the stented site (27). However, in our study, no significant differences were observed between the diabetic and non-diabetic patients in the occurrence rates of early, late, very late thrombosis, and overall thrombosis. These findings differ to those reported previously. This may be due to the difference between the patient selection and the detailed design of the studies.

Diabetes induces a prothrombotic state that is correlated with high platelet activity and high levels of coagulation factors, including tissue factor, fibrinogen, and plasminogen activator inhibitor 1. Thus, the potentially increased risk of ST is an important caveat for coronary DES implantation. Preventive modalities are crucial for diabetic patients after PCI. The importance of regular medical therapy according to guidelines in these patients should be emphasized and intensively monitored, including the use of antithrombotic drugs (dual antiplatelet therapy with aspirin and clopidogrel or ticagrelor), insulin, and the aggressive modification of cardiovascular risk factors, glycemic control, and intensive statins (29).

This study had several limitations. First, the study was

Table 2 Clinical outcomes at the 1-, 3- and 5-year follow-up (n, %)

Outcomes	Diabetic patients (n=173)	Non-diabetic patients (n=407)	P value
1-year follow-up (0–1 year)			
Death	7 (4.0)	10 (2.5)	0.30
Cardiac death	6 (3.5)	5 (1.5)	0.22
Re-MI	1 (0.6)	2 (0.5)	0.79
TLR	1 (0.6)	12 (3.0)	0.14
Bleeding events	1 (0.6)	0 (0)	0.3
Thrombotic	2 (1.1)	3 (0.7)	0.99
Non-cardiac death	1 (0.6)	4 (0.9)	0.99
MACE	8 (4.6)	18 (4.4)	0.91
3-year follow-up (1–3 years)			
Death	7 (4.0)	7 (1.7)	0.17
Cardiac death	1 (0.6)	3 (0.7)	0.74
Re-MI	1 (0.6)	4 (1.0)	0.99
TLR	8 (4.6)	14 (3.4)	0.49
Bleeding events	1 (0.6)	2 (0.5)	0.79
Thrombotic	2 (1.1)	0 (0)	0.09
Non-cardiac death	6 (3.5)	4 (1.0)	0.08
MACE	10 (5.8)	21 (5.2)	0.76
5-year follow-up (3–5 years)			
Death	11 (6.4)	8 (2.0)	0.01
Cardiac death	3 (1.7)	3 (0.7)	0.52
Re-MI	3 (1.7)	0 (0)	0.02
TLR	10 (5.8)	16 (3.9)	0.32
Bleeding events	0 (0)	3 (0.7)	0.34
Thrombotic	3 (1.7)	3 (0.7)	0.52
Non-cardiac death	8 (4.6)	5 (1.2)	0.02
MACE	16 (9.2)	19 (4.4)	0.03
0–3 years follow-up			
Death	14 (8.1)	17 (4.2)	0.06
Cardiac death	7 (4.0)	9 (2.2)	0.34
Re-MI	2 (1.2)	6 (1.5)	0.93
TLR	9 (5.2)	26 (6.4)	0.58
Bleeding events	2 (1.2)	2 (0.5)	0.74
Thrombotic	4 (2.3)	3 (0.7)	0.24
Non-cardiac death	7 (4.0)	8 (2.0)	0.25
MACE	18 (10.4)	39 (9.6)	0.76

Table 2 *(continued)*

Table 2 *(continued)*

Outcomes	Diabetic patients (n=173)	Non-diabetic patients (n=407)	P value
0–5 years follow-up			
Death	25 (14.5)	25 (6.1)	0.00
Cardiac death	10 (5.8)	12 (2.9)	0.10
Re-MI	5 (2.9)	6 (1.5)	0.42
TLR	19 (11.0)	42 (10.3)	0.81
Bleeding events	2 (1.2)	5 (1.2)	0.73
Thrombotic	7 (4.0)	6 (1.5)	0.11
Non-cardiac death	15 (8.7)	13 (3.2)	0.00
MACE	34 (19.7)	58 (14.3)	0.10

Re-MI, re-myocardial infarction; TLR, target lesion revascularization; MACE, major adverse cardiac event.

Table 3 ST in 2 groups over 5 years

ST	Diabetic patients (n=173)	Non-diabetic patients (n=407)	P value
Definite ST, n (%)			
Early	1 (0.6)	1 (0.2)	0.51
Late	0 (0.0)	1 (0.2)	0.70
Very late	2 (1.2)	2 (0.5)	0.74
Overall	3 (1.7)	4 (1.0)	0.73
Probable ST, n (%)			
Early	2 (1.2)	2 (0.5)	0.74
Late	1 (0.6)	1 (0.2)	0.51
Very late	1 (0.6)	3 (0.7)	0.99
Overall	4 (2.3)	6 (1.5)	0.72
Definite or probable ST, n (%)			
Early	3 (1.7)	3 (0.7)	0.52
Late	1 (0.6)	2 (0.5)	0.79
Very late	3 (1.7)	5 (1.2)	0.93
Overall	7 (4.0)	10 (2.5)	0.30

ST, stent thrombosis.

not a randomized controlled trial, and as a single-center study, it has its limitations. Second, revascularization procedures remote from the target vessel were not part of the present analysis. Third, the sample size of the study was small.

In conclusion, the study showed that compared to non-diabetic patients, diabetic patients have an increased risk of mortality after revascularization with DES during the long-term follow-up period. Conversely, there were no differences in terms of the risks of MACE, MI, and TLR between the diabetic and non-diabetic patients. An increasing trend was observed in the MACE rate in both the diabetic and nondiabetic patients who received DES implantations, but the rate of the diabetic patients increased

faster than that of the non-diabetic patients, especially in the long-term.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at https://atm.amegroups.com/article/view/10.21037/atm-22-4517/rc

Data Sharing Statement: Available at https://atm.amegroups.com/article/view/10.21037/atm-22-4517/dss

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://atm.amegroups.com/article/view/10.21037/atm-22-4517/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Ethics Committee of Chinese PLA General Hospital (No. S2020-012-03). Informed consent was taken from all the patients.

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